

Attorney Docket No. 1999.452 US C1

REMARKS

Upon entry of the above amendment, claims 6-11 will be pending in the instant application. Claims 6 and 9 are independent. Applicants have made a clerical correction to claim 8. Applicants respectfully submit that no new matter issues have been raised.

Issue Under Double Patenting

Claims 6-10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,682,745. The Examiner states that the US '745 would allow a skilled artisan to have a reasonable expectation of success of using the instant application as claimed.

Applicants request that the double patenting rejection be held in abeyance until allowable subject matter is identified. Applicants will entertain submitting a Terminal Disclaimer at this time.

Attorney Docket No. 1999.452 US CI

Issue under Double Patenting

Claims 6-8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,120,775.

Applicants request that the double patenting rejection be held in abeyance until allowable subject matter is identified. Applicants will entertain submitting a Terminal Disclaimer at this time.

Issue under 35 U.S.C. §112, First Paragraph

Claims 6-11 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly fails to describe subject matter that is claimed. Applicants traverse this assertion.

The present invention is directed toward a method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine (claim 9) and a method for administering a live attenuated bacterial vaccine to a mammal (claim 6). The Examiner asserts that every live attenuated vaccine must have a written description. Applicants disagree with the Examiner's interpretation of the scope of the claims.

Attorney Docket No. 1999.452 US C1

The objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). "The subject matter of the claim need not be described literally . . . in order for the disclosure to satisfy the description requirement." MPEP §2163.02.

As stated above, Applicants must describe the present invention clearly to allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. Applicants have shown that representative live attenuated bacterial strains can be administered by injection into the submucosal tissue. These representative examples clearly disclose that Applicants had possession of the claimed invention.

The invention as claimed is a method or process of vaccinating mammals in a particular manner. Applicants are not claiming actual vaccines of live attenuated bacterial strains.

Applicants, respectfully, request the Examiner withdraw the 35 U.S.C. §112, first paragraph, rejection.

Attorney Docket No. 1999.452 US C1

Issue Under 35 U.S.C. §112

Claims 6-11 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, "while being enabling for a method for protecting a mammal against Streptococcus equi infection by administering a live attenuated Streptococcus equi strain (TW980), does not reasonably provide enablement for a method for protecting a mammal against all bacterial infection by administering any and all live attenuated bacterial strains." Applicants traverse the Examiner's interpretation of the present invention and 35 U.S.C. §112, first paragraph.

Claims 6 and 9 recite a method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine (claim 9) and a method for administering a live attenuated bacterial vaccine to a mammal (claim 6). The Examiner has incorrectly asserted that the claims are for "a method of protecting a mammal from a bacterial infection." The present invention is a method of administering a bacterial vaccine.

Applicants assert that the method of administering by injection a bacterial vaccine into the submucosal tissue is fully enabled.

Attorney Docket No. 1999.452 US C1

The invention is in the unexpected advantageous characteristics of the submucosal tissue, facilitating a good antigen presentation while preventing the development of large abscesses or lesions. The submucosal tissue is by nature thin and soft, and is lined on one side by vascular tissue, and on the other by thin and soft mucosal epithelium. Mucosal tissue is found in the mouth, the nose, the lining of the gut, the eye, the vulva and the lips. Applicants have found that the excellent vascularization on the one side provides an ideal location for antigen presentation to the bloodstream and lymphatic tissues, while the delicacy of the covering mucosal epithelium leads to a transient rupture of bacterial abscesses or lesion at the injection site. Thus, the mucosal epithelium layer ruptures before pressure can build up and large pustules can form.

Example 1 discloses that submucosal administration of an immunogenically effective amount of the live attenuated bacterial strain completely protected against infection, thus reasonably enabling a method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine (claim 9) and a method for administering a live attenuated bacterial vaccine to a mammal (claim 6).

"As long as the specification discloses at least one method for making or using the claimed invention that bears a

Attorney Docket No. 1999.452 US C1

reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied." In re Fisher, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA).

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." In re Buchner, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991). A skilled artisan would understand the present invention as defined by claims 6 and 9 as being a method for reducing the amount of adverse reactions in a mammal at an injection site of a live attenuated bacterial vaccine (claim 9) and a method for administering a live attenuated bacterial vaccine to a mammal (claim 6).

A skilled artisan would not suffer an undue burden of experimentation to practice the present invention. When a viable live attenuated bacterial vaccine is at hand, administration by injection is clearly enabled. Thus, Applicants respectfully request the withdrawal of the 35 U.S.C. §112, first paragraph, rejection.

### Conclusion

Applicants submit that the present claims define patentable subject matter and are in condition for allowance.

Attorney Docket No. 1999.452 US C1

Should the Examiner believe that a conference would be helpful in advancing the prosecution of this application, he is invited to telephone Applicants' Attorney at the number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,



Mark W. Milstead  
Attorney for Applicants  
Registration No. 45,825

Akzo Nobel Patent Department.  
Intervet Inc.  
29160 Intervet Lane  
Millsboro, DE 19966  
Tel: (302) 934-4395  
Fax: (302) 934-4305

Attorney Docket No. 1999.452 US/C1  
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PAGE 12/12 \* RCVD AT 4/11/2005 4:01:52 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXRF-1/5 \* DNIS:8729306 \* CSID:3029344305 \* DURATION (mm-ss):02-36